

ISTITUTO NAZIONALE DI FISICA NUCLEARE

CONSIGLIO DIRETTIVO

DELIBERAZIONE N. 12201

Il Consiglio Direttivo dell'Istituto Nazionale di Fisica Nucleare, riunito in Roma nei giorni 26 e 27 gennaio 2012 alla presenza di n. 34 dei suoi componenti su un totale di n. 34;

- premesso che, in base all'art. 2 del proprio Statuto, l'Istituto Nazionale di Fisica Nucleare promuove, coordina ed effettua la ricerca scientifica nel campo della fisica nucleare, subnucleare, astroparticellare e delle interazioni fondamentali, nonché la ricerca e lo sviluppo tecnologico pertinenti all'attività in tali settori, prevedendo forme di sinergia con altri enti di ricerca e il mondo dell'impresa;
- premesso che, nel perseguimento della propria missione, l'Istituto Nazionale di Fisica Nucleare, promuove e partecipa a collaborazioni, stipula convenzioni e contratti in materia di studio, ricerca e servizi con enti, società ed imprese pubbliche e private, nazionali, comunitari, stranieri e organizzazioni internazionali;
- premesso che la Best Medical International, Inc. è un'azienda produttrice e distributrice di dispositivi medici e isotopi radioattivi, che conduce attività di ricerca e sviluppo nel campo dei radiofarmaci;
- premesso che l'Istituto Nazionale di Fisica Nucleare, nell'ambito di una ricerca tesa allo sviluppo di nuovi bersagli per acceleratori ad alta intensità, ha avviato una collaborazione con la Best Theratronics di Ottawa Canada (BTL) per la fornitura di un ciclotrone da 70 MeV da installarsi presso i Laboratori Nazionali di Legnaro;
- vista la nota della Best Theratronics del 12 maggio 2011 con la quale il Presidente di detta società ha espresso l'interesse per una collaborazione scientifica con l'Istituto nel campo dei radiofarmaci;
- esaminata la proposta di "Memorandum of Understanding" allegato alla presente deliberazione;
- vista la nota del Direttore dei Laboratori Nazionali di Legnaro del 17 novembre 2011, prot. n. 3548, con la quale il Direttore ha espresso parere favorevole in merito alla collaborazione scientifica proposta;
- premesso che l'onere finanziario derivante all'Istituto dallo schema di "Memorandum of Understanding between Best Medical International, Inc. and

Istituto Nazionale di Fisica Nucleare” di cui alla presente deliberazione, consiste nelle normali spese di funzionamento, che trovano copertura con le assegnazioni attribuite ai Laboratori Nazionali di Legnaro negli esercizi di competenza;

- su proposta della Giunta Esecutiva;
- in data 26 gennaio 2012 con n. 34 voti favorevoli;

DELIBERA

Di approvare lo schema di “Memorandum of Understanding between Best Medical International, Inc and Istituto Nazionale di Fisica Nucleare”, allegato alla presente deliberazione di cui costituisce parte integrante e sostanziale. Il Presidente, o persona da lui delegata, è autorizzato a negoziarlo e sottoscriverlo.

**Memorandum of Understanding between
Best Medical International, Inc.
and
Istituto Nazionale di Fisica Nazionale**

1. This Memorandum of Understanding between Best Medical International, Inc. having offices at 7643 Fullerton Road, Springfield, VA 22153 (hereinafter referred to as "BEST") and Istituto Nazionale di Fisica Nazionale having offices at Via Enrico Fermi 40, 00400 Frascati, Italy (hereinafter referred to as "INFN") sets forth an agreement between Best and INFN to collaborate on the projects as described in Appendix A. This Agreement shall take effect upon the date of last signature.
2. BEST is a manufacturer and distributor of medical devices and radioactive isotopes and conducts research and development activities.
3. INFN is an Italian Governmental Agency responsible for the Italian research in the fields of sub-nuclear, nuclear and astro-particles physics and, in his capacity, promotes the necessary research and development activities in such fields.
4. NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein and intending to be legally bound, the parties hereby agree as follows:
5. BEST and INFN seek to engage in a series of projects related to target and chemistry research and development. Specifically, the Parties plan to conduct research and development in medical radioisotope high power production targets, radioisotope separation techniques and radionuclides pharmaceutical production. Appendix A describes the details of the work to be performed, the allocation of responsibilities between the Parties, and a general timeframe for performance.
6. BEST and INFN will work jointly to create a written report documenting findings and conclusions based on the results of the projects.
7. Except as otherwise agreed upon in a separate written document signed by both parties, each Party shall assume sole financial responsibility for any and all expenses incurred by said Party during the performance of this Agreement.
8. BEST shall solely own all right, title, and interest in Intellectual Property conceived or reduced to practice entirely by one or more employees of BEST or by those under a legal obligation to assign IP rights to BEST.
9. INFN shall solely own all right, title, and interest in Intellectual Property conceived or reduced to practice entirely by one or more employees of INFN or by those under a legal obligation to assign IP rights to INFN.
10. BEST and INFN jointly own all right, title, and interest in Intellectual Property conceived or reduced to practice jointly by one or more employees of BEST and one or more employees of INFN. BEST and INFN agree to negotiate in good faith on licensing issues related to any IP developed under this Agreement.
11. BEST and INFN define with further agreement issues like patenting and licenses for pre-industrialization and industrialization production and commercialization of common IP results.
12. BEST and INFN shall each designate one (or more) staff member(s) responsible for maintaining close contact with the other institute in order to ensure the implementation of the collaborative research program.

13. Documents addressed to INFN shall be sent to:

Dr. Gianfranco Prete
INFN - Laboratori Nazionali di Legnaro
Viale dell'Università 2
35020 Legnaro (PADOVA)
ITALY.

Documents addressed to BEST shall be sent to:

Best Medical International, Inc.
7643 Fullerton Road,
Springfield, VA 22153

or such successors as each Party may designate and communicate in writing to the other Party.

14. Each Party warrants to the other that it is duly authorized to enter into this Agreement and that the terms of this Agreement are not inconsistent with any of its respective outstanding contractual obligations.
15. Although the Parties anticipate that their relationship will be longstanding and that future joint projects will be forthcoming, the execution and performance of this Agreement does not obligate the Parties to enter into any other agreement or to perform any obligations other than as specified herein.
16. This Agreement shall be construed under and governed by the courts and laws Italy, without giving effect to the conflicts of laws provision thereof.

Istituto Nazionale di Fisica Nucleare

Best Medical International, Inc.

By: _____

By: _____

Signature: _____

Signature: _____

Title: _____

Title: _____

Date: _____

Date: _____

Appendix A to the Memorandum of Understanding between Best Medical International, Inc. and Istituto Nazionale di Fisica Nazionale

This agreement presents the collaboration items which have been identified so far

The Parties will define the costs sharing of each item with further detailed agreement.

This agreement covers the following projects and may be amended as required:

Project 1 - Passivation project

The project shall use thin film deposition techniques to provide a chemically passive interior surface to radioisotope production target assemblies.

Project Activities

- 1.1. Stage 1: Coat the interior of a preformed "hemispherical" target window with Niobium to provide a chemical barrier to reactions occurring during proton bombardment for radioisotope production.
 - 1.1.1. BEST to supply preformed substrates
 - 1.1.2. INFN to coat Niobium thickness adequate for a chemical barrier
 - 1.1.3. BEST and INFN to perform cold and radioactive characterization experiments
 - 1.1.4. Results to be published in open literature after any needed IP protection.
- 1.2. Stage 2: Coat the interior of radioisotope production vessels for chemical passivation using thin film techniques.
 - 1.2.1. BEST to supply substrate vessels
 - 1.2.2. INFN to create appropriate thin film apparatus configuration for coating vessels
 - 1.2.3. BEST and INFN to characterize completed assembly with cold and radioactive experiments
 - 1.2.4. Results to be published in open literature after any needed IP protection.
- 1.3. Stage 3: Develop thin film protective surfaces for radio isotope production targets that use liquid metals as the production material.
 - 1.3.1. BEST and INFN to supply target and system concept
 - 1.3.2. BEST to supply prototype vessel
 - 1.3.3. INFN to thin film coat the prototype vessel
 - 1.3.4. BEST and INFN to characterize the coating with cold and radioactive tests
 - 1.3.5. Results to be published in open literature after any needed IP protection.

Project Schedule

TBD with BEST

Project Responsible

INFN: Dr. Vincenzo Palmieri, INFN

BEST: _____

Copia conforme
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Project 2 - Accelerator production of Tc99m

This project purpose is to provide experimental measurement to validate the feasibility of accelerator produced Tc99m as a viable alternative way compared to current reactor-produced Mo99/Tc99m generators.

With this demonstration the project will provide a commercial solution for turnkey processing of Tc99m and then continue to provide evidence required for marketing authorization.

Project Activities

2.1. Stage 1: Measurement of reaction channels associated with proton bombardment of Molybdenum-100 enriched targets. Determine the levels of contaminant activity, relative to Tc99m, due to the other radioisotopes produced.

2.1.1. BEST to supply Mo-100 enriched target material

2.1.2. INFN to supply variable energy proton beams experimental setup.

2.1.3. INFN and BEST to perform measurement of excitation function for the reaction channels of interest

2.1.4. Results to be published in open literature

2.2. Stage 2: Develop a production process that can be adapted to central pharmacy cyclotrons.

2.2.1. BEST to supply production target holders

2.2.2. BEST and INFN to develop target material coating processes

2.2.3. BEST and INFN to test process with cold and radioactive experiments at Belgian and Italian laboratories.

2.2.4. Results to be published in open literature after needed IP protection.

2.3. Stage 3: Provide supporting documentation and data for Italian Marketing Authorization.

2.3.1. BEST to supply final turnkey system

2.3.2. INFN to provide Standard Operating Procedure experimental verification using Italian laboratories.

2.3.3. BEST to provide Standard Operating Procedure experimental verification using Belgian laboratories.

2.3.4. Results to be published in open literature after needed IP protection.

Project Schedule

2012: Target prototype realization and in vivo Tc99m imaging tests to assess influence of Tc99m/Tc99 atomic ratios as expected from accelerator-based production;

2013: Target prototype termo-mechanical and reliability test under beam and experimental production measurement of 99Mo and optimization of radiochemical process;

2014: Experimental Tc99m production measurement and optimization of radiochemical process.

Project Responsible

INFN: Dr. Eng. Juan Esposito, INFN

BEST: _____